

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 21-1317-GBW-SRF
)	
IVANTIS, INC., ALCON RESEARCH)	
LLC, ALCON VISION, LLC, and ALCON)	
INC.,)	
)	
Defendants.)	

LETTER TO THE HONORABLE GREGORY B. WILLIAMS
FROM ANDREW E. RUSSELL

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Dear Judge Williams:

Plaintiff Sight Sciences, Inc. (“Sight”) seeks to exclude all evidence of Defendants’ obviousness-type double patenting (“ODP”) defense from trial, “an ‘extreme’ sanction not normally to be imposed absent a showing of willful deception or ‘flagrant disregard’ of a court order.” *Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 905 (3d Cir. 1977) (*Pennypack*). Sight has failed to justify this extreme sanction.

Defendants’ ODP argument is not late. Defendants disclosed their ODP contentions ***more than a month before*** the Court-ordered deadline for final invalidity contentions—a deadline that Sight agreed to. Sight cannot show good cause to amend the scheduling order to undo the final invalidity contentions deadline it agreed to. Moreover, Defendants timely pled ODP as an affirmative defense, phrased in a standard way that courts have held is sufficient.

To the extent that the Court nonetheless holds that Defendants’ contentions were untimely—despite being served more than a month before the agreed-on final contentions deadline and adequately pled—Sight fails to show, under the *Pennypack* factors, that Defendants’ important ODP defense would delay or disrupt trial or otherwise prejudice Sight. Sight cannot support its baseless allegation of bad faith and gamesmanship because—as Sight knows—Defendants developed and disclosed their ODP contentions after a change in the law. Striking Defendants’ ODP contentions would only permit Sight to unjustly extend its monopoly on its purported invention beyond the time permitted by statute, and the Court should reject Sight’s effort to do so.

I. Defendants’ ODP Contentions Are Not Untimely Because They Were Served Several Weeks Before the Court’s Deadline

Sight ignores that under the Court’s Scheduling Order—containing deadlines to which Sight previously agreed—Defendants’ final invalidity contentions are not due until November 20, 2023 (60 days from the Court’s September 19, 2023 claim construction order). D.I. 93 at ¶ 9(f); D.I. 287. Defendants served their ODP contentions on October 12 (D.I. 304), shortly after *In re Collect* and 39 days *before* the parties’ agreed-on deadline for final invalidity contentions. 81 F.4th 1216 (Fed. Cir. 2023); *Align Tech., Inc. v. 3Shape A/S*, C.A. No. 17-1647-LPS, D.I. 236 (D. Del. Oct. 17, 2019) (Hall, J.) (Ex. A) (denying motion to strike new invalidity contentions from final contentions where party complied with the final contention deadline in the scheduling order).

Now, Sight insists that Defendants should face an “extreme” sanction for doing exactly what this Court’s order allows: amending its invalidity contentions. *Pennypack*, 559 F.2d at 905; D.I. 93 at ¶ 9(f). Sight has shown no good cause for changing the parties’ agreed deadline as set in the Court’s scheduling order and no basis to find those contentions untimely. *See* Fed. R. Civ. P. 16(b)(4) (requiring “good cause” to amend a scheduling order). The Court should deny Sight’s request.

II. Defendants Disclosed ODP Contentions Shortly After *In re Collect* Changed the Law

Sight faults Defendants for failing to disclose ODP in their *initial* invalidity contentions, or in response to an interrogatory asking for Defendants to identify faults in Plaintiff’s §§ 102 and 103 contentions. But Defendants could not have disclosed a theory that was contrary to law at the time. Further, ODP is not responsive to the interrogatory Sight relies on, which sought contentions under §§ 102 and 103, not under ODP, a judicially-created doctrine with roots in § 101.

Before *In re Collect*, ODP did not apply to patents like the Patents-in-Suit, which have different expiration dates due to PTA. In *Novartis AG v. Ezra Ventures LLC*, the Federal Circuit declined to allow ODP, “a judge-made doctrine,” to “cut off a statutorily-authorized time extension” such as a patent term extension under 35 U.S.C. § 156 (“PTE”). 909 F.3d 1367, 1375 (Fed. Cir. 2018) (“*Novartis*”). Applying *Novartis*, district courts declined to apply ODP to override PTA. *See, e.g., Amgen, Inc. v. Sandoz Inc.*, C.A. No. 18-11026 (MAS) (DEA), 2021 U.S. Dist. LEXIS 224304, at *85 (D.N.J. Sep. 20, 2021) (citing *Novartis* to hold that “[a] difference in expiration dates between two patents that arises solely from a statutorily authorized time extension, such as a patent-term adjustment pursuant to 35 U.S.C. § 154(b) or a patent-term extension pursuant to 35 U.S.C. § 156, cannot be the basis for an application of ODP”); *Mitsubishi Tanabe Pharma Corp. v. Sandoz, Inc.*, 533 F. Supp. 3d 170, 214 (D.N.J. 2021) (citing *Novartis* and declining to apply ODP to a patent subject to PTA because it would “cut off a statutorily-authorized time extension”).

Not until August 28, 2023, in *In re Collect*, did the Federal Circuit address whether *Novartis* applies to PTA. 81 F.4th at 1227-29. *Amicus* briefs supported the parties on both sides of the issue. *See id.* at 1225-26 (listing *amici* for each side). At least one case in this district deferred ruling on ODP pending the *In re Collect* decision. *Robocast, Inc. v. Youtube, LLC*, C.A. No. 22-304-RGA, 2022 U.S. Dist. LEXIS 205907, at *9 (D. Del. Nov. 14, 2022) (dismissing ODP motion with leave to re-file after the Federal Circuit decided “the interplay between obviousness-type double-patenting and a patent term extension” in the then-pending *In re Collect* case). Indeed, even *Sight’s* counsel recognized—outside of this litigation—that *In re Collect* held that PTA must be added before conducting the ODP invalidity analysis, after *Novartis* had held PTE should not be added for the ODP analysis. *See Ex. B, Federal Circuit’s In re Collect Decision Deals Blow to Patent Term Adjustment*, COOLEY (Oct. 17, 2023), <https://www.cooley.com/news/insight/2023/2023-10-17-federal-circuits-in-re-collect-decision-deals-blow-to-patent-term-adjustment>.

Ultimately, the court in *In re Collect* announced that “there is no conflict between ODP and § 154 [PTA].” 81 F.4th at 1227. When it issued, *In re Collect* reversed *Amgen* and *Mitsubishi*, which had declined to apply ODP to patents based on PTA. In this district, for example, Judge Andrews recognized that *In re Collect* announced a rule regarding ODP. *See Allergan USA, Inc. v. MSN Labs. Private Ltd.*, C.A. No. 19-1727-RGA, 2023 U.S. Dist. LEXIS 172641, at *60 (D. Del. Sep. 27, 2023) (finding claim that was subject to PTA invalid for ODP following *In re Collect*).

Sight incorrectly relies on *AbbVie Inc. v. Mathilda and Terence Kennedy Inst. of Rheumatology Tr.*, 764 F.3d 1366, 1373 (Fed. Cir. 2014) (“*AbbVie*”) to argue that the Federal Circuit had applied ODP to patents subject to PTA for “[n]early ten years.” D.I. 307 at 2. *AbbVie* mentioned § 154 (governing PTA) only in passing, when identifying the problem that “[p]atents claiming overlapping subject matter that were filed at the same time still can have different patent terms due to examination delays at the PTO.” 764 F.3d at 1373. The patents at issue in *AbbVie* were subject to ODP due to their different filing dates, not to PTA, and the brief mention of § 154 is dicta.

Moreover, *Novartis* came four years after *AbbVie*, and directly addressed ODP in the context of PTE—holding that it cannot apply. 909 F.3d at 1375. *Sight* cites a single district court case in the interim between *Novartis* and *AbbVie*, but that case is meaningless given that *Novartis* later changed the rule (and, regardless, the parties in that case apparently did not dispute that ODP applied in the context of PTA). *Magna Elecs., Inc. v. TRW Auto. Holdings Corp.*, C.A. No. 12-654, 2015 U.S. Dist. LEXIS 182044, at *7-10 (W.D. Mich. Dec. 10, 2015). The obscure appellate

briefing and International Trade Commission opinion Sight relies on are similarly beside the point. *See* D.I. 307 at 2; *id.*, Ex. 10. A brief does not change the law; neither does speculating about what the Federal Circuit *might* do.

Thus, from the beginning of this case until the Federal Circuit issued *In re Collect*, *Novartis* was the governing rule, and courts in the Third Circuit applied it to preclude ODP for patents subject to PTA. After the Federal Circuit's holding in *In re Collect*, Defendants promptly developed and disclosed their ODP defense within just over a month and did so well before the agreed and Court-ordered deadline for Defendants to amend their invalidity contentions. *See* D.I. 307, Ex. 1 (Oct. 2, 2023 letter notifying Sight of Defendants' ODP position).

Sight faults Defendants for not supplementing their response to Sight's interrogatory 13. D.I. 307 at 1. But Defendants' ODP contentions are not responsive to that interrogatory. Sight's interrogatory 13 seeks only responses *regarding* §§ 102 and 103—which does not encompass ODP, a judicially-created doctrine with its roots in § 101. *See* D.I. 307, Ex. 8 (Sight's interrogatory 13 regarding Defendants' interrogatory 8); Ex. C (showing Defendants' interrogatory 8 sought Sight's bases for invalidity under 35 U.S.C. §§ 102 and 103); *In re Collect*, 81 F.4th at 1216. Regardless, even if ODP had been responsive, Defendants had no duty to supplement because their contentions were “otherwise . . . made known to [Sight] during the discovery process” under Federal Rule of Civil Procedure 26(e)(1)(A) when Defendants disclosed them. D.I. 304.

Ultimately, each of Sight's challenges to the timeliness of Defendants' ODP disclosure fail. The parties have known for months that final contentions would be served *after* the close of fact discovery, yet Sight never objected until now. Defendants, however, timely amended their invalidity contentions because it was within the Court-ordered deadline and because they were promptly served after *In re Collect* created a fundamental change in law.

III. Defendants Pled ODP in Their Answer to Plaintiff's Second Amended Complaint

Sight is also wrong that Defendants did not plead ODP as an affirmative defense. Defendants pled obviousness-type double patenting in their Second Amended Answer in the same way that they pled their other invalidity defenses:

SECOND DEFENSE (INVALIDITY)

The Patents-in-Suit are invalid for failure to satisfy one or more of the conditions and requirements of patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including, but not limited to, 35 U.S.C. **§§ 101**, 102, 103, and/or 112, or under any of the **judicially created doctrines of invalidity**.

D.I. 77 at 25 (emphases added). Obviousness-type double patenting “is a judicially created doctrine that has its roots in 35 U.S.C. § 101.” *In re Collect*, 81 F.4th at 1226.

Sight never took issue with the level of disclosure of any of the invalidity defenses in Defendants' Answer, and never moved to strike the Answer's reference to judicially-created doctrines of invalidity. Defendants' affirmative defense of invalidity is sufficient to preserve its claim. *See, e.g., STC. UNM v. Intel Corp.*, C.A. No. 10-1077 RB/WDS, 2012 U.S. Dist. LEXIS 192494, at *3-5, *11 (D.N.M. May 8, 2012) (declining to strike affirmative defense of invalidity under the

“judicially created doctrines of invalidity,” and holding that a counterclaim of invalidity under “35 U.S.C. §§ 101 et. seq.” “provides notice sufficient to satisfy the requirements of Rule 8(a)” as long as the defendant later identifies specific statutory bases); *Sanofi-Aventis U.S. LLC v. Eli Lilly & Co.*, C.A. 14-113-RGA, D.I. 26 at 4:2-5:8 (D. Del. Apr. 14, 2014) (Ex. D) (Judge Andrews declining to strike a counterclaim alleging invalidity, including under judicially-created doctrines of invalidity and unenforceability, finding that “it looks like every other invalidity counterclaim I’ve ever seen.”); *id.*, D.I. 13 at 4, 11 (Ex. E) (brief showing language of counterclaim at issue).

Finally, even if Defendants’ Answer did not sufficiently disclose its ODP defense, good cause exists to grant leave to allow Defendants to amend. Defendants have good cause to modify the scheduling order under Federal Rule of Civil Procedure 16 in light of *In re Collect*’s change in the law, and Sight cannot articulate prejudice that would preclude that amendment under Federal Rule of Civil Procedure 15. “The court should freely give leave [to amend] when justice so requires,” and “[t]he Third Circuit has adopted a liberal approach to the amendment of pleadings to ‘ensure[] that a particular claim will be decided on the merits rather than on technicalities.’” *Arneault v. Diamondhead Casino Corp.*, 277 F. Supp. 3d 671, 674 (D. Del. 2017).

IV. Sight Fails to Show That The *Pennypack* Factors Warrant Exclusion

Because Defendants timely disclosed their ODP contentions well in advance of the parties’ agreed final contention deadline, *Pennypack* does not apply. The Court should hold Sight to its agreement. To the extent the Court holds otherwise, however, the *Pennypack* factors favor admission of these important contentions.

Factor 1: Defendants’ ODP Defense Is Important. Defendants’ ODP contentions are an important defense, invalidating all 28 asserted claims of two patents-in-suit. D.I. 297 at 18-24, Appx. X-Y; *see Intermec Techs. Corp. v. Palm Inc.*, C.A. No. 07-272-SLR, 2010 U.S. Dist. LEXIS 55624, at *6 (D. Del. June 7, 2010) (“Invalidity is [an] important defense to infringement.”); *Ateliers de la Haute-Garonne v. Broetje Automation-USA, Inc.*, 817 F. Supp. 2d 394, 398 (D. Del. 2011) (finding best mode theory disclosed after the close of fact discovery “extremely important” where it “implicate[d] every asserted claim of both patents-in-suit”).

Moreover, “[c]ourts in the Third Circuit favor resolution of disputes on their merits, particularly with respect to patent validity issues, which raise public interest concerns extending beyond the immediate dispute between the parties.” *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 93 (D. Del. 2016). ODP is important to prevent a patentee like Sight from achieving an improper extension of its patent term. *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1577 (Fed. Cir. 1996). Striking Defendants’ ODP contentions would permit Sight to unjustly extend its damages period by nearly one and a half years. *See* D.I. 297, App. Y.

Factors 2 and 4: Defendants’ Disclosure of Their ODP Defense Does Not Prejudice Sight. Sight cries foul over Defendants disclosing their ODP defense after the close of fact discovery because Sight could not “develop evidence or elicit testimony from fact or expert witnesses.” D.I. 307 at 3. But ODP is a question of law and, here, it is resolved by a simple comparison of the claims; one that Sight itself already did when it admitted the patents are not patentably distinct. *See In re Collect*, 81 F.4th at 1222 (“ODP is a question of law.”); D.I. 297, 20-24 and Appendices X-Y (comparing claims). Defendants do not rely on expert testimony or facts beyond Sight’s

admissions and the patents themselves. *See* D.I. 297, 20-24 and Appendices X-Y. Sight has articulated no specific evidence it would have elicited from fact witnesses to resolve this question of law, nor what expert testimony it would have offered. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, C.A. No. 21-691-GBW, D.I. 270 at 11 (D. Del. Dec. 19, 2022) (Ex. F) (“[U]nfairness alone does not rise to prejudice favoring exclusion.”).

Factor 3: Defendants’ ODP Defense Does Not Disrupt Trial. Defendants served their ODP contentions before the deadline for final contentions, and trial is not set until April 8, 2024 (D.I. 93)—six months from Defendants’ disclosure of their ODP defense. *See Withrow v. Spears*, 967 F. Supp. 2d 982, 1005 (D. Del. 2013) (holding, less than three months before trial, that “there is sufficient time for . . . prejudice to be mitigated without disrupting trial”). Sight offers a rote statement that Defendants’ ODP defense would disrupt trial, but does not explain how. The evidence Defendants rely on is already in the record, and Defendants offer no new facts or expert testimony because none are needed. This question of law can be fully resolved via summary judgment on the existing record.

Factors 5 & 6: Defendants Acted in Good Faith and Disclosed Their ODP Defense After a Change in the Law. Sight accuses Defendants of bad faith and “gamesmanship” for not seeking leave to amend their Answer, and for having “no legitimate explanation” for disclosing their ODP contentions after the close of fact discovery. First, Defendants’ answer discloses their ODP defense in the same way that it discloses all of Defendants’ invalidity defenses, and no amendment is necessary. Second, Defendants disclosed their ODP defense soon after *In re Collect* changed the law to permit that defense. Sight relies on *AbbVie* to suggest that Defendants could have asserted the defense prior to *In re Collect*, but as explained above, *AbbVie* held no such thing (and, regardless, *Novartis* succeeded it and held to the contrary).

Sight relies on *Engineered Prods. Co. v. Donaldson Co.* to accuse Defendants of “gamesmanship,” but that case involved different circumstances. 147 F. App’x 979 (Fed. Cir. 2005). There, the defendant withheld its ODP allegation until plaintiff had voluntarily dismissed a second patent, so that it could entirely preclude the plaintiff’s infringement allegations. *Id.* at 986-87. The court found “some smack of gamesmanship” because defendant waited to assert its unpled ODP defense until after plaintiff no longer had the option to proceed on the second patent. *Id.* at 986. Here, in contrast, Defendants pled ODP and properly disclosed their ODP contentions shortly after *In re Collect* enabled them, before the deadline for final invalidity contentions, and had nothing to gain by withholding those contentions. *See In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 793 (3d Cir. 1994) (reversing bad faith determination where, *inter alia*, the party “had little to gain from the . . . delay”). Plaintiff cannot support its allegations of bad faith and gamesmanship.

V. The Court Should Deny Plaintiff’s Motion to Strike Defendants’ Timely-Disclosed ODP Defense

Defendants timely disclosed their ODP contentions immediately after they were formed, following *In re Collect*, and well over a month before the deadline for final invalidity contentions. Defendants also timely asserted judicially-created doctrines of invalidity, including ODP, in their Answer. Defendants respectfully request that the Court deny Sight’s motion to strike.

Respectfully submitted,

/s/ Andrew E. Russell

Andrew E. Russell (No. 5382)

cc: Clerk of the Court (via CM/ECF & Hand Delivery)
All Counsel of Record (via CM/ECF & Email)